

WHAT IS CLAIMED IS:

1 1. A method of treating a patent foramen ovale in a heart, the method
2 comprising:

3 advancing a catheter device to a position in the heart for treating the patent
4 foramen ovale;

5 bringing tissues adjacent the patent foramen ovale at least partially together
6 using the catheter device; and

7 applying energy to the tissues with the catheter device to substantially close
8 the patent foramen ovale acutely.

1 2. A method as in claim 1, wherein the tissues are brought together before
2 applying the energy.

1 3. A method as in claim 2, further comprising holding the tissues together
2 while applying the energy.

1 4. A method as in claim 3, further comprising holding the tissues together
2 after the energy has been applied to allow them to cool.

1 5. A method as in claim 4, further comprising:
2 moving at least part of the catheter device to a different position relative to the
3 tissues;

4 bringing the tissues at least partially together again; and
5 applying energy to the tissues again.

1 6. A method as in claim 5, further comprising repeating the moving,
2 bringing together and applying energy steps at multiple locations along the patent foramen
3 ovale.

1 7. A method as in claim 6, wherein the repeated moving, bringing
2 together and applying energy steps are started at a first side of the patent foramen ovale and
3 continued across the patent foramen ovale to a second side.

1 8. A method as in claim 7, further comprising biasing at least part of the
2 catheter device toward the first side, using a biasing device on the catheter, before first
3 bringing the tissues together.

1 9. A method as in claim 7, wherein moving at least part of the catheter
2 body comprises bringing the tissues together between two energy transmission members,
3 wherein the tissues are brought together against a catheter body of the catheter device, and
4 wherein bringing the tissues together against the catheter body pushes the catheter body to the
5 different position.

1 10. A method as in claim 7, wherein moving at least part of the catheter
2 device comprises moving at least one energy transmission member to the different position.

1 11. A method as in claim 10, wherein moving at least part of the catheter
2 device comprises moving two energy transmission members to the different position.

1 12. A method as in claim 11, wherein moving at least part of the catheter
2 device further comprises moving a catheter body to the different position.

1 13. A method as in claim 4, further comprising actively cooling the tissues
2 after the energy has been applied.

1 14. A method as in claim 1, wherein advancing the catheter comprises
2 positioning a first distal portion of the catheter in a right atrium of the heart.

1 15. A method as in claim 14, wherein advancing further comprises
2 advancing a second distal portion of the catheter at least partially through the patent foramen
3 ovale.

1 16. A method as in claim 15, further comprising advancing the second
2 distal portion through the patent foramen ovale into the left ventricle.

1 17. A method as in claim 15, further comprising retracting a catheter body
2 or sheath to expose at least the second distal portion.

1 18. A method as in claim 15, wherein bringing the tissues at least partially
2 together comprises applying force to the tissues by manipulating at least one of the first and
3 second distal portions.

1 19. A method as in claim 18, wherein bringing the tissues together
2 comprises:

manipulating one of the first and second distal portions to apply force to the tissues; and
maintaining the other of the first and second distal portions in a relatively stable position to act as a surface against which to bring the tissues together.

20. A method as in claim 18, wherein bringing the tissues together comprises moving the first and second distal portions towards one another to bring the tissue together between them.

21. A method as in claim 18, wherein bringing the tissues together comprises expanding at least one expandable member on at least one of the first and second distal portions.

22. A method as in claim 21, wherein bringing the tissues together comprises:
expanding a first expandable member on the first distal portion; and
expanding a second expandable member on the second distal portion.

23. A method as in claim 22, further including moving at least one of the first and second expandable members axially along the catheter device toward the other expandable member to bring the tissues together between them.

24. A method as in claim 18, wherein manipulating at least one of the first and second distal portions comprises advancing at least one of the portions into one of the tissues adjacent the patent foramen ovale.

25. A method as in claim 24, wherein the first distal portion is advanced into septum secundum tissue.

26. A method as in claim 25, wherein the second distal portion is advanced into septum primum tissue, and wherein the first and second distal portions are brought together to bring the tissues together.

27. A method as in claim 16, wherein bringing the tissues together comprises applying attractive magnetic force between the first and second distal portions.

1 28. A method as in claim 1, wherein advancing the catheter comprises
2 advancing an expandable distal portion of the catheter at least partially through the patent
3 foramen ovale, the expandable distal portion disposed within a sheath.

1 29. A method as in claim 28, wherein bringing the tissue together
2 comprises retracting the sheath to expose the expandable distal portion, thus allowing it to
3 expand to bring the tissues together between portions of the expandable member.

1 30. A method as in claim 1, wherein applying energy comprises applying
2 at least one of radiofrequency energy, cryogenic energy, resistive heat energy, ultrasound
3 energy, microwave energy and laser energy.

1 31. A method as in claim 30, wherein at least one of monopolar
2 radiofrequency energy and bipolar radiofrequency energy is applied.

1 32. A method as in claim 30, wherein applying energy comprises
2 energizing a single conductive member of the catheter device.

1 33. A method as in claim 30, wherein applying energy comprises
2 energizing multiple conductive members of the catheter device.

1 34. A method as in claim 30, wherein applying energy comprises:
2 energizing at least one conductive fluid in the catheter device; and
3 releasing the conductive fluid from the catheter device to contact the tissues.

1 35. A method as in claim 34, wherein energizing the conductive fluid
2 comprises applying radio frequency energy to the fluid disposed within at least one
3 expandable member of the catheter device.

1 36. A method as in claim 35, wherein the fluid comprises saline solution.

1 37. A method as in claim 35, wherein releasing the conductive fluid
2 comprises allowing the fluid to pass out of at least one aperture in the at least one expandable
3 member.

1 38. A method as in claim 37, further comprising introducing fluid into the
2 expandable member.

1 39. A method as in claim 1, wherein applying energy comprises denaturing
2 collagen in the tissues.

1 40. A method as in claim 1, further comprising monitoring an amount of
2 energy applied to the tissues.

1 41. A method as in claim 40, wherein monitoring the amount of energy
2 comprises monitoring a temperature of the tissues.

1 42. A method as in claim 40, wherein monitoring the amount of energy
2 comprises monitoring an impedance of the tissues.

1 43. A method as in claim 40, further comprising determining when a
2 sufficient amount of energy has been applied to the tissues to substantially close the patent
3 foramen ovale acutely.

1 44. A method as in claim 43, further comprising discontinuing the
2 application of energy when the sufficient amount of energy has been applied.

1 45. A method as in claim 1, further comprising directly visualizing the
2 patent foramen ovale and the tissues using at least one visualization device coupled with the
3 catheter device.

1 46. A method of treating a patent foramen ovale in a heart, the method
2 comprising:
3 advancing a catheter device to a position in the heart for treating the patent
4 foramen ovale;
5 bringing tissues adjacent the patent foramen ovale at least partially together
6 using the catheter device;
7 applying energy to the tissues with the catheter device while holding the
8 tissues at least partially together; and
9 holding the tissues at least partially together for a sufficient time after applying
10 the energy to substantially close the patent foramen ovale.

1 47. A catheter device for treating a patent foramen ovale in a heart, the
2 catheter device comprising:

3 an elongate catheter body having a proximal end and a distal end;
4 at least one tissue apposition member at or near the catheter body distal end
5 for bringing tissues adjacent the patent foramen ovale at least partially together; and
6 at least one energy transmission member at or near the distal end for applying
7 energy to the tissues to substantially close the patent foramen ovale acutely.

1 48. A catheter device as in claim 47, wherein the at least one tissue
2 apposition member comprises at least a first tissue apposition member for contacting tissue
3 adjacent the patent foramen ovale from a right atrium of the heart.

1 49. A catheter device as in claim 48, wherein the at least one tissue
2 apposition member further comprises at least a second tissue apposition member for
3 contacting tissue adjacent the patent foramen ovale from the right atrium.

1 50. A catheter device as in claim 49, wherein the first and second tissue
2 apposition members comprise opposable jaws, and wherein at least one of the first and
3 second members is advancable through tissue adjacent the patent foramen ovale.

1 51. A catheter device as in claim 50, wherein the first apposition member
2 advances through septum secundum tissue and the second apposition member advances
3 through septum primum tissue.

1 52. A catheter device as in claim 48, wherein the at least one tissue
2 apposition member further comprises at least a second tissue apposition member for
3 advancing through the patent foramen ovale to contact the tissues from a left atrium of the
4 heart.

1 53. A catheter device as in claim 52, wherein at least one of the first and
2 second tissue apposition members comprises an expandable member.

1 54. A catheter device as in claim 53, wherein both the first and second
2 tissue apposition members comprise expandable members, and wherein at least one of the
3 expandable members is slidably disposed along the catheter body so as to be axially movable
4 toward the other expandable member.

1 55. A catheter device as in claim 53, wherein at least one expandable
2 member includes at least one aperture for releasing conductive fluid to contact the tissues.

1 56. A catheter device as in claim 55, wherein at least one expandable
2 member includes a plurality of small apertures for releasing the conductive fluid.

1 57. A catheter device as in claim 55, wherein one of the first and second
2 members comprises an expandable member and the other of the first and second members
3 comprises a deployable shaped portion, wherein the expandable member and the shaped
4 portion are brought together to bring the tissues together.

1 58. A catheter device as in claim 57, wherein the deployable shaped
2 portion comprises a shape memory material that changes from an undeployed to a deployed
3 shape when released from the catheter body.

1 59. A catheter device as in claim 52, wherein the first and second tissue
2 apposition members comprise a clamp for clamping the tissues together.

1 60. A catheter device as in claim 52, wherein the first tissue apposition
2 member has a first deployed shape and the second tissue apposition member has a second
3 deployed shape, and wherein the first and second members, when deployed to contact the
4 tissues, caused the tissues to be brought together.

1 61. A catheter device as in claim 60, wherein the first shape comprises
2 approximately a curved hook for curving over an edge of the patent foramen ovale to apply
3 force to the tissues from the left atrium, and wherein the second shape comprises
4 approximately a straight, linear shape for applying pressure to the tissues from the right
5 atrium.

1 62. A catheter device as in claim 52, wherein the first and second tissue
2 apposition members comprise magnets having opposite polarity.

1 63. A catheter device as in claim 52, wherein the first tissue apposition
2 member comprises a pair of opposable jaws for contacting the septum secundum from the
3 right atrium, and the second tissue apposition member comprises a curved member for
4 advancing through the patent foramen ovale to contact the septum primum from the left
5 atrium.

1 64. A catheter device as in claim 47, wherein the at least one tissue
2 apposition member comprises:
3 at least two tissue apposition members for moving relative to one another to
4 bring the tissues together between them; and
5 at least one biasing member for biasing the tissue apposition members toward
6 a first side of the patent foramen ovale.

1 65. A catheter device as in claim 64, wherein the tissue apposition
2 members are movable along the patent foramen ovale from the first side to a second opposite
3 side of the patent foramen ovale.

1 66. A catheter device as in claim 65, wherein the catheter body has a cross-
2 sectional shape such that when the tissues are brought together between the two tissue
3 apposition members, the tissues urge the catheter body to a different position relative to the
4 patent foramen ovale.

1 67. A catheter device as in claim 66, wherein the shape is selected from the
2 group consisting of triangular, oval, elliptical and diamond shaped.

1 68. A catheter device as in claim 66, wherein the two tissue apposition
2 members comprise:
3 one shape-memory tissue apposition member; and
4 one jaw member.

1 69. A catheter device as in claim 66, further comprising at least one
2 aperture on the catheter body for releasing one or more fluids to enhance the application of
3 energy to the tissues to close the patent foramen ovale.

1 70. A catheter device as in claim 66, further comprising a coating over the
2 catheter body, the coating enhancing application of energy to the tissues when the tissues
3 contact the catheter body.

1 71. A catheter device as in claim 47, wherein the at least one tissue
2 apposition member comprises an expandable member releasably disposed within the catheter
3 body, wherein advancing the expandable member out the distal end of the catheter body or

4 retracting the catheter body relative to the expandable member allows the expandable
5 member to expand within the patent foramen ovale.

1 72. A catheter device as in claim 71, wherein the expandable member
2 comprises two prongs that expand apart to provide lateral force to the tissues adjacent the
3 patent foramen ovale.

1 73. A catheter device as in claim 72, wherein the prongs do not extend into
2 the left atrium of the heart.

1 74. A catheter device as in claim 72, wherein the prongs are spring loaded.

1 75. A catheter device as in claim 72, wherein the prongs comprise a shape
2 memory material.

1 76. A catheter device as in claim 72, wherein the prongs include at least
2 one vacuum aperture for applying vacuum force to further bring the tissues together.

1 77. A catheter device as in claim 47, further comprising a guide member
2 for advancing through the patent foramen ovale, wherein the catheter device is slidably
3 disposed over the guide member.

1 78. A catheter device as in claim 77, wherein the guide member comprises
2 a guidewire divided along a portion of its length, the divided portion comprising expandable
3 shape memory material.

1 79. A catheter device as in claim 77, wherein the guide member comprises
2 at least one tip for contacting a left atrial surface of the tissues adjacent the patent foramen
3 ovale.

1 80. A catheter device as in claim 79, wherein the at least one tip is
2 conformable to the left atrial surface.

1 81. A catheter device as in claim 79, wherein the guide member is
2 retractable to engage the at least one tip with the left atrial surface.

1 82. A catheter device as in claim 77, wherein the guide member comprises
2 at least one of the energy transmission member(s).

1 83. A catheter device as in claim 82, wherein the guide member comprises
2 an expandable member for expanding within the patent foramen ovale, and wherein the
3 expandable member comprises at least one radiofrequency energy transmission member.

4 84. A catheter device as in claim 47, wherein the at least one energy
5 transmission member transmits at least one of radiofrequency energy, cryogenic energy,
6 resistive heat energy, ultrasound energy, microwave energy and laser energy.

1 85. A catheter device as in claim 84, wherein the at least one energy
2 transmission member is movable relative to the at least one tissue apposition member.

1 86. A catheter device as in claim 84, wherein the at least one energy
2 transmission member is coupled with the at least one tissue apposition member.

1 87. A catheter device as in claim 84, wherein the at least one energy
2 transmission member comprises the at least one tissue apposition member.

1 88. A catheter device as in claim 84, wherein the at least one energy
2 transmission member comprises at least one monopolar radiofrequency transmission member.

1 89. A catheter device as in claim 84, wherein the at least one energy
2 transmission member comprises at least two bipolar radiofrequency transmission members.

1 90. A catheter device as in claim 84, wherein the at least one energy
2 transmission member comprises:

3 at least one radiofrequency transmission member disposed within an
4 expandable member, the expandable member including at least one aperture for releasing
5 fluid to contact the tissues; and

6 at least one conductive fluid disposed within the expandable member and
7 exposed to the radiofrequency transmission member.

1 91. A catheter device as in claim 84, wherein the at least one energy
2 transmission member comprises at least one curved radiofrequency transmission member.

1 92. A catheter device as in claim 84, wherein the at least one energy
2 transmission member comprises at least one of a mesh material and a braid material.

1 93. A catheter device as in claim 47, wherein the at least one energy
2 transmission member comprises a guide member for advancing through the patent foramen
3 ovale.

1 94. A catheter device as in claim 93, wherein the guide member includes at
2 least one expandable portion for expanding within the patent foramen ovale to at least
3 partially bring together the tissues adjacent the patent foramen ovale.

1 95. A catheter device as in claim 47, further comprising at least one sensor
2 coupled with the catheter device for sensing an amount of energy delivered to the tissues by
3 the at least one energy transmission member.

1 96. A catheter device as in claim 95, wherein the at least one sensor is
2 selected from the group consisting of an infrared sensing device, thermistors and
3 thermocouples.

1 97. A catheter device as in claim 95, further comprising a microprocessor
2 coupled with the at least one sensor for processing sensed data to determine when the amount
3 of delivered energy has reached a desired amount of energy.

1 98. A catheter device as in claim 47, further comprising a microprocessor
2 coupled with the catheter device for sensing and controlling energy transmission by the
3 energy transmission member.

1 99. A system for treating a patent foramen ovale in a heart, the system
2 comprising:

3 a catheter device comprising:

4 an elongate catheter body having a proximal end and a distal end;

5 at least one tissue apposition member at or near the catheter body distal
6 end for bringing tissues adjacent the patent foramen ovale at least partially together; and

7 at least one energy transmission member at or near the distal end for
8 applying energy to the tissues to substantially close the patent foramen ovale; and

9 at least one guide member for guiding the catheter device to a position for
10 treating the patent foramen ovale.

11 100. A system as in claim 99, wherein the at least one tissue apposition
12 member comprises at least a first tissue apposition member for contacting tissue adjacent the
13 patent foramen ovale from a right atrium of the heart.

1 101. A system as in claim 100, wherein the at least one tissue apposition
2 member further comprises at least a second tissue apposition member for contacting tissue
3 adjacent the patent foramen ovale from the right atrium.

1 102. A system as in claim 101, wherein the first and second tissue
2 apposition members comprise opposable jaws, and wherein at least one of the first and
3 second members is advancable through tissue adjacent the patent foramen ovale.

1 103. A system as in claim 102, wherein the first apposition member
2 advances through septum secundum tissue and the second apposition member advances
3 through septum primum tissue.

1 104. A system as in claim 100, wherein the at least one tissue apposition
2 member further comprises at least a second tissue apposition member for contacting tissue
3 adjacent the patent foramen ovale from a left atrium of the heart.

1 105. A system as in claim 104, wherein the second tissue apposition
2 member is advancable through the patent foramen ovale into the left atrium to contact the
3 tissue.

1 106. A system as in claim 105, wherein at least one of the first and second
2 tissue apposition members comprises an expandable member.

1 107. A system as in claim 106, wherein both the first and second tissue
2 apposition members comprise expandable members, and wherein at least one of the
3 expandable members is slidably disposed along the catheter body so as to be axially movable
4 toward the other expandable member.

1 108. A system as in claim 106, wherein at least one expandable member
2 includes at least one aperture for releasing conductive fluid to contact the tissues.

1 109. A system as in claim 108, wherein at least one expandable member
2 includes a plurality of small apertures for releasing the conductive fluid.

1 110. A system as in claim 108, wherein one of the first and second members
2 comprises an expandable member and the other of the first and second members comprises a
3 deployable shaped portion, wherein the expandable member and the shaped portion are
4 brought together to bring the tissues together.

1 111. A system as in claim 110, wherein the deployable shaped portion
2 comprises a shape memory material that changes from an undeployed to a deployed shape
3 when released from the catheter body.

1 112. A system as in claim 104, wherein the first and second tissue apposition
2 members comprise a clamp for clamping the tissues together.

1 113. A system as in claim 99, wherein the at least one tissue apposition
2 member comprises:
3 at least two tissue apposition members for moving relative to one another to
4 bring the tissues together between them; and
5 at least one biasing member for biasing the tissue apposition members toward
6 a first side of the patent foramen ovale.

1 114. A system as in claim 113, wherein the tissue apposition members are
2 movable along the patent foramen ovale from the first side to an opposite side of the patent
3 foramen ovale.

1 115. A system as in claim 99, wherein the at least one tissue apposition
2 member comprises an expandable member releasably disposed within the catheter body,
3 wherein advancing the expandable member out the distal end of the catheter body allows the
4 expandable member to expand within the patent foramen ovale.

1 116. A system as in claim 115, wherein the expandable member comprises
2 at least two members that expand apart to provide lateral force to the tissues adjacent the
3 patent foramen ovale.

1 117. A system as in claim 116, wherein the exposed expanding member
2 provides the lateral force without extending into the left atrium of the heart.

1 118. A system as in claim 116, wherein the expandable member comprises a
2 spring loaded member.

1 119. A system as in claim 116, wherein the expandable member comprises a
2 shape memory material.

1 120. A system as in claim 99, wherein the guide member is advancable
2 through the patent foramen ovale, wherein the catheter device is slidably disposed over the
3 guide member.

1 121. A system as in claim 120, wherein the guide member comprises a
2 guidewire divided along a portion of its length, the divided portion comprising expandable
3 shape memory material.

1 122. A system as in claim 121, wherein the guide member comprises at
2 least one tip for contacting a left atrial surface of the tissues adjacent the patent foramen
3 ovale.

1 123. A system as in claim 122, wherein the at least one tip is conformable to
2 the left atrial surface.

1 124. A system as in claim 122, wherein the guide member is retractable to
2 engage the at least one tip with the left atrial surface.

1 125. A system as in claim 99, wherein the at least one energy transmission
2 member transmits at least one of radiofrequency energy, cryogenic energy, resistive heat
3 energy, ultrasound energy, microwave energy and laser energy.

1 126. A system as in claim 125, wherein the at least one energy transmission
2 member is movable relative to the at least one tissue apposition member.

1 127. A system as in claim 125, wherein the at least one energy transmission
2 member is coupled with the at least one tissue apposition member.

1 128. A system as in claim 127, wherein the at least one energy transmission
2 member comprises at least one monopolar radiofrequency transmission member.

1 129. A system as in claim 127, wherein the at least one energy transmission
2 member comprises at least two bipolar radiofrequency transmission members.

1 130. A system as in claim 127, wherein the at least one energy transmission
2 member comprises:

3 at least one radiofrequency transmission member disposed within an
4 expandable member, the expandable member including at least one aperture for releasing
5 fluid to contact the tissues; and

6 at least one conductive fluid disposed within the expandable member and
7 exposed to the radiofrequency transmission member.

1 131. A system as in claim 127, wherein the at least one energy transmission
2 member comprises at least one curved radiofrequency transmission member.

1 132. A system as in claim 127, wherein the at least one energy transmission
2 member comprises at least one of a mesh material and a braid material.

1 133. A system as in claim 99, further comprising at least one sensor coupled
2 with the catheter device for sensing an amount of energy delivered to the tissues by the at
3 least one energy transmission member.

1 134. A system as in claim 133, wherein the at least one sensor is selected
2 from the group consisting of an infrared sensing device, thermistors and thermocouples.

1 135. A system as in claim 133, further comprising a microprocessor coupled
2 with the at least one sensor for processing sensed data to determine when the amount of
3 delivered energy has reached a desired amount of energy.

1 136. A system as in claim 99, further comprising a microprocessor coupled
2 with the catheter device for sensing and controlling energy transmission by the energy
3 transmission member.